RFP NO. NIMH-00-DS-0004

TITLE: "Follow-Up of the Multimodal Treatment Study of Children with Attention Deficit Hyperactivity Disorder (MTA)"

ISSUED BY: Robert D. Barnie
Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-8030

DATE ISSUED: April 26, 2000

PROPOSAL DUE DATE: July 24, 2000

Dear Sirs:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-00-DS-0004. Proposals are being solicited under Sole Source Procedures from the following clinical sites which make up the MTA Group:

NYU, Child Study Center, NY, NY
Duke University Medical Center, Durham, NC
New York State Psychiatric Institute, NY, NY
University of California at Berkeley, Berkeley, CA
University of Pittsburgh, Western Psychiatric Institute and Clinic, Pittsburgh, PA
University of California at Irvine, Irvine, CA
McGill University, Montreal Children's Hospital, Montreal, Quebec

It is expected that seven (7) non-competitive cost-reimbursement, completion contracts will be awarded on or before October 31, 2000 with a base period of five (5) years and one (1) 2-year option. **However, award is dependent on the approval of the Justification for Other Than Full and Open Competition. Other sources have 45 days to respond to the synopsis that was published in the Commerce Business Daily on April 12, 2000.**

The RFP does not commit the Government to pay costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with any acquisition action.

SPECIAL ATTENTION SHOULD BE DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS & BUSINESS PROPOSAL INSTRUCTIONS CONTAINED IN ATTACHMENT 4.

The documents included with this RFP package are as follows:

I. Streamlined RFP

A. Statement of Work (SOW) (Attachment 1)
B. Deliverables and Reporting Requirements (Attachment 2)
C. Evaluation Factors for Contract Award (Attachment 3)

II. Specific RFP Instructions and Provisions (Attachment 4)

III. Applicable RFP References (Attachment 5)

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

Your proposal must be signed by an official authorized to contractually bind your organization and must indicate that it is valid for a period of at least 120 days. One (1) original and ten (10) copies of your technical proposal and one (1) original and four (4) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN 3:30 P.M., LOCAL PREVAILING TIME ON July 24, 2000, at one of the following addresses:

If hand-delivered or delivery service	If using U.S. Postal Service
Contracting Officer National Institute of Mental Health Contracts Management Branch 6001 Exec. Blvd., Rm. 6107, MSC 9603 Rockville, MD 20852-9603	Contracting Officer National Institute of Mental Health Contracts Management Branch 6001 Exec. Blvd., Rm. 6107, MSC 9603 Bethesda, MD 20892-9603

In addition, you are reminded that the "Technical Proposal Cover Sheet" (contained in Attachment 5) must be completed in full detail and used as the cover sheet for each copy of your technical proposal. New policies require submission of more detailed information than previously required. It is important that you list all professional personnel and organizations named in the proposal who will have any role in the proposed work, including: staff of the primary organization (offeror), subcontractors, collaborating organizations, and consultants. Organizational affiliation(s) must be indicated for every person named. You may use additional sheets, as needed, following the format shown in the Technical Proposal Cover Sheet. This information will be used to ensure that there will be no conflicts of interest when selecting review committee members.

Your attention is further directed to the "Proposal Intent Response Sheet" contained in Attachment 4. Please complete this form and return it to this office either via mail (to the above address), by fax on (301) 443-0501 or by E-mail at Rb245s@.nih.gov on or before June 16, 2000. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABE ONLY ON THE INTERNET (REFER TO THE NIMH HOME PAGE) AT:
http://www.nimh.nih.gov/grants/indexcon.cfm

Questions concerning any areas of uncertainty, which in your opinion, require clarification or correction, must be furnished in writing (Fax or e-mail is also acceptable) to Robert D. Barnie, and marked "Offeror's Questions, RFP No. NIMH-00-DS-0004". If you have any additional questions regarding this RFP, please contact me by e-mail at Rb245s@.nih.gov, by telephone at (301) 443-2696 or by Fax at (301) 443-0501. Collect calls will not be accepted. ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL(S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Sincerely,

/s/

Robert D. Barnie, Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Attachments: 1-5

ATTACHMENT 1 to STREAMLINED RFP No. NIMH-00-DS-0004

Statement of Work

Title: "Follow-Up of the Multimodal Treatment Study of Children with Attention Deficit Hyperactivity Disorder (MTA)"

1. Background

Attention deficit hyperactivity disorder (ADHD) is a common condition affecting about 3-5% of school age children. Though developmentally determined, ADHD often persists into adolescence and can affect behavior and functioning even in adults. As determined also by associated comorbidity, children with ADHD are at increased risk for educational underachievement, delinquent behavior, substance abuse, and lower occupational status. Ongoing treatment is usually required for years, at least in the first 2 decades of life. Effective pharmacological and psychosocial treatments exist, but their long-term effects have not been adequately studied in terms of both effectiveness and safety. For instance, it is not known if treatment of ADHD symptoms results in improved educational achievement, decreased antisocial behavior, reduced substance abuse, or better occupational status. Likewise, it is not known if exposure to amphetamine-like stimulant medications for extended periods of time during development may carry negative consequences, as manifested by an increased use of illicit drugs (possibly through a mechanism of amphetamine-induced behavioral sensitization), higher incidence of mania, psychosis, or other manifestations of psychopathology. Naturalistic follow-up of clinical samples exist, but the results are limited by lack of appropriate controls. On the other hand, testing these hypotheses in controlled experiments poses formidable methodological, ethical, and feasibility obstacles. There is a considerable interest in the long-term effects of treatments of ADHD that underscores the public health importance of research in this area. The consensus statements at the end of the NIH Consensus Development Conference on the Diagnosis and Treatment of ADHD in 1998 emphasized the need for such studies (NIH 1998). Following-up on this recommendation, the NIMH has hosted a workshop to discuss both basic and clinical research on the long-term effects of the therapeutic use of stimulants in ADHD in early December 1999. The workshop included discussion of opportunities provided by the MTA for addressing some of these questions and recommendations to follow-up the MTA sample were made.

2. Aims of the Contract

The purpose of this contract is to study the long-term effects of different treatment modalities for children with attention deficit hyperactivity disorder (ADHD) through a systematic follow-up of the subjects who participated in the Multimodal Treatment Study of Children with ADHD (MTA). The major research questions that should be considered in planning the MTA follow-up include:

A. What is the impact over time of the 14-month exposure to treatment modalities, which were different in type and intensity, on:

- Persistence of ADHD symptoms

- Incidence of psychopathology (i.e., non-ADHD psychiatric disorders, such as depression, mania, psychosis)

- Incidence of early substance use, substance abuse, and substance dependence (targeted as separate outcomes)

- Incidence of delinquent behaviors

- Educational achievement

- Incidence of other adverse outcomes (harm from accidents, suicidal behaviors, aggressive acts)

- Utilization of mental health and medical services

- Utilization of court-mandated services

- Utilization of special education services

B. How do the services actually received compare, in terms of type and quality, to the "ideal standard" set by the treatment received during the clinical trial?

C. What are the possible moderators and mediators of obtaining (or not obtaining) appropriate and adequate mental health and educational services? For instance, the following are to be considered:

    - structural (e.g., access barriers, coordination, comprehensiveness)
    - parent/child characteristics (e.g., income, insurance status, education; attitudes, knowledge, cultural factors; degree of improvement at the end of the controlled clinical trial)?
    - process of care factors (e.g., continuity; technical, interpersonal aspects; participatory decision making)
    - perceived outcomes

D. What are the cost implications (e.g., cost/benefit ratios) of intensive treatments for children with ADHD? How do these treatment costs relate to costs later expended in special education, juvenile justice, mental health, or substance abuse settings?

E. What is the impact of 14-month sustained treatment of prepubertal ADHD children with high, moderate, and low doses of amphetamine-like stimulants on:

- Risk for anxiety, mood disorders, tics, eating disorders

- Risk for substance abuse and dependence

- Growth (growth speed, puberty)

3. General Requirements

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary qualified personnel, facilities, materials, supplies, equipment, and services, not otherwise provided by the Government, as needed to perform the Statement of Work..

All the work shall be conducted in coordination with the other clinical sites making up the MTA Group (which shall operate on this project as a research network) and in conjunction with the Data Management Center. The seven clinical sites making up the MTA Group are: NYU Child Study Center, NY, NY; Duke University Medical Center, Durham, NC; University of Pittsburgh, Western Psychiatric Institute and Clinic, Pittsburgh, PA; University of California at Berkeley, Berkeley, CA; New York State Psychiatric Institute and Clinic, NY, NY; University of California at Irvine, Irvine, CA; and McGill University, Montreal Children's Hospital, Quebec, Canada. The Data Management Center will be determined after award of this contract.

All work under the contract shall be conducted under the general guidance of the Government Project Officer (GPO) whose position is defined in Section G of the contract.

4. Work Plan

In conjunction with the other members of the MTA Group, develop a Work Plan which outlines how and when the work will be accomplished.

5. Finalization of the Study Protocol and Consent/Assent Forms

The members of the MTA Group shall work together to finalize the draft protocol (submitted in your technical proposal) based on the input from the technical reviewers, the scientific advisors, consultants, and the GPO. At a minimum, the final protocol shall include the following aspects:

- a review of the study objectives and endpoints;
- primary and secondary outcomes;
- frequency of assessments;
- sample size and power estimates;
- outline of the plan for patient follow-up;
- plans for assessing patients who are difficult to reach;
- plans for training raters and interviewers;
- monitoring of the quality of data collection;
- human subjects considerations (e.g., plans for managing patients at risk for self-injury, violence, or abuse);
- consent and assent forms;
- plans for final data analysis; and
- plans for subject reimbursement

This task shall be completed within 4 months from the award date of the contract.

Implementation of the study protocol shall not begin without first obtaining the written authorization of the Government's Project Officer.

6. **The Contractor shall implement the approved Final Protocol by undertaking the following tasks:**

a. Assist the Data Management Center in Preparing the Study Forms and Database

There will be a Data Management Center, separate from this contract. The Data Management Center will be responsible for preparing study forms and arranging for the database where the data will be entered. The Contractor shall assist the Data Management Center in these tasks by providing input on their content and format during the initial phases of the contract as well as through out the life of the contract , as needed.

b. Train Staff in Data Collection

The Contractor shall coordinate with the Data Management Center and arrange for the training of its entire staff involved in data collection and handling. This task shall be completed within 5 months from the award date of the contract.

c. Study Sample Maintenance

In order to minimize attrition, the Contractor shall maintain contacts with the MTA study participants at its site over the duration of the contract. (If the patient flow falls below the minimum required for meaningful statistical analysis, under the contract, the Government may elect to terminate the contract for convenience. If the sample size for the entire study (to include all 7 members of the MTA Group) falls below meaningful statistical analysis the Government reserves the right to terminate all contracts, making up the MTA Group, for convenience). The study under this contract is a follow-up collection of information from a previously developed research sample. The contract has no provisos for delivery of any treatment to the study participants. If , during the process of interviewing and data collection, the Contractor becomes aware of the need for treatment of any of the study participants, appropriate referrals shall be made for treatment outside the study being conducted under this contract. The Contractor shall have appropriate staff available that are trained to handle possible emergency situations, when immediate intervention may be necessary.

d. Data Collection and Handling

The Contractor shall arrange for all the necessary steps and conduct all the necessary work for collecting the data (from study subjects affiliated with their clinic) that are required for addressing the study research hypotheses. These tasks include, but are not limited, to the following:

1. Contact the study participants to schedule their interviews for data collection, and provide reimbursements to study participants as appropriate.

2. Conduct interviews and collect all relevant data (from subjects, schools etc.).

3. Check the data for completeness and accuracy.

4. Store data in a safe place and protect the confidentiality of the study participants.

5. Arrange for data entry and the electronic transfer of data to the Data Management Center, or duplication and transfer of study forms to the Data Management Center (as arranged in coordination with the Data Management Center).

e. Data Analyses and Reporting

The Contractor, in coordination with the other clinical sites (making up the MTA Group), the Data Management Center, the GPO, consultants and scientific experts, shall instruct and assist the Data Management Center in the data analyses and shall prepare scientific reports suitable for publication in peer-reviewed journals. (Scientific experts are appointed by the GPO to assist with scientific decisions related to the study).

f. Meetings/Communications

The following tasks will be performed at different times throughout the duration of the contract, as specified below:

1. The Contractor shall participate in telephone conferences calls with the other clinical sites, the Data Management Center, the GPO, other NIMH staff, advisors, and other staff involved in the study, in order to discuss the progress of the study, or other project related activities. The frequency of these calls shall depend upon the phase of the study, complexity of issues, actual progress, and problems encountered; it is estimated that calls will occur monthly during the early phase of the study and once every two months as the study progresses. (The Data Coordinator shall prepare minutes and summaries of the calls, as appropriate).

2. Schedule, coordinate, arrange, participate in, and provide any information necessary for the Steering Committee meetings. (The Steering Committee shall oversee the scientific aspect of how the study is conducted and shall consist of the Principal Investigator from each member of the MTA Group and the GPO (who will coordinate the Steering Committee's activities)). These meetings will have an average frequency of about once every 18 months, as required by the phases and progress of the study.

3. The Contractor shall plan to attend approximately one meeting a year, as deemed necessary by the GPO.

g. Technical Provisions

1. All tasks described in this statement of work shall be coordinated and implemented by the Contractor in conjunction with and under the guidance of the GPO.

2. The data collected under this contract shall belong to the Government. It is understood that the Contractors, working in conjunction with the Data Management Center, the GPO, scientific experts, and consultants, shall expeditiously prepare reports on the study results for publication in peer-reviewed scientific journals. These publication activities shall be coordinated by an ad hoc constituted Publication Committee, which shall include representatives of the Contractors, Data Management Center, and the GPO. No publications or release of data shall take place without the approval of the Publication Committee and the GPO until all the primary papers have been published. After all the primary papers have been published, a copy of the database will be made available directly to each P.I. involved in the study and other reports for publication may be produced without the approval of the GPO, but with appropriate acknowledgment of the contract as the source of the data. (Refer to HHSAR Clause 352.270-6 "Publication and Publicity" and the Clause entitled "Publication and Publicity" located in Section H of the contract.)

3. It is anticipated that the GPO and other NIMH staff, actively involved in the scientific aspects of the study, shall publish study data jointly with the Contractors and clinical sites' P.I.s.

4. The Contractor shall establish procedures to safeguard the confidentiality of any clinical information. Refer to the Clauses entitled "Privacy Act" and "Confidentiality of Information" located in Section H of the contract, for details regarding the safeguarding of confidential information.

7. Reporting Requirements and Deliverables

In addition to any ad hoc reports requested by the GPO, the Contractor shall submit the Reports and Deliverables outlined below.

a. Work Plan

Within 14 days of contract award and in conjunction with the other members of the MTA Group a "Work Plan" shall be developed (and a copy provided to the GPO) which outlines how and when the work will be accomplished.

b. Quarterly Study Reports

The Contractor shall submit one copy to the GPO and one copy to the Contracting Officer (CO) of the quarterly report. These reports shall be due within 15 days of the close of the reporting period throughout the life of the contract. At a minimum this report shall include a description of the study progress, subjects contacted and interviewed, subjects lost to follow-up and reasons for attrition, their demographic characteristics, quality of data, information on complications and problems encountered and their

resolution. Problems encountered and plans for correcting attrition must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution are to be included.

c. Final Protocol

In conjunction with the other member of the MTA Group, a copy of the approved final protocol shall be provided to the GPO immediately following approval.

d. IRB Approved Consent Documents

IRB approved consent documents shall be provided to the GPO immediately following approval.

e. Annual Report for Gender/Minority Tracking

Annually, the Contractor shall submit one copy to the GPO of a recruiting report detailing gender and ethnicity (American Indian or Alaskan Natives; Asian or Pacific Islanders; Black, Not of Hispanic Origin; White, Not of Hispanic Origin; Other or Unknown) of the study sample that has been assessed.

f. Study Final Report

The Contractor shall submit to the GPO two hard copies and one electronic copy (in PC format) of the Final Report on or before the contract completion date. The CO shall also receive one hard copy of this report. This report shall include a summation of the work performed and results obtained. This report shall be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form.

g. Other Materials

The contractor shall provide deliverables and materials as required by the study and the GPO. Examples of such deliverables and material include, but are not limited to, material to support the request for a clinical exemption to the Paperwork Reduction Act requirements and reports for NIMH monitoring boards and scientific experts.

8. **Non-Reimbursable Contract Costs**

Costs of clinical care, such as patient bed costs, outpatient visit fees and clinical laboratory determinations shall not be reimbursed under this contract.

9. **Options**

Unless the Government exercises its option pursuant to the Option Clause set forth below, the contract will consist only of years 1 through 5. Pursuant to clause 52.217-9 set forth below, the

Government may, by unilateral contract modification, require the Contractor to perform additional Years of the Statement of Work. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in Article B.

Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days. The preliminary notice does not commit the Government to an extension.

(c) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause shall not exceed 7 years.

(End of Clause)

ATTACHMENT 2 to STREAMLINED RFP No. NIMH-00-DS-0004

DELIVERABLES AND REPORTING REQUIREMENTS

1. DELIVERIES OR PERFORMANCE

Performance of this contract shall begin on the effective date and shall not extend beyond the estimated completion date of the contract unless the period is extended by modification to the contract.

2. DELIVERY SCHEDULE

A. After the contract award date, the Contractor shall deliver the following items/reports to the GPO in accordance with the delivery schedule set forth below:

ITEM/DESCRIPTION	QUANTITY	DUE DATE
1. Work Plan	2	14 days after contract award date
2. Quarterly Study Reports	2	15 days after the close of each reporting period
3. Final Protocol	2	Immediately following approval
4. IRB Approved Consent Document	2	Immediately following approval
5. Annual Report for Gender/ Minority Tracking	2	15 days after each anniversary date
6. Draft Final Report	2	One month prior to contract expiration Date
7. Final Report	2	By contract expiration date
8. Other Materials	2	As required by the GPO
9. Draft Publications	2	Before submitting for publication

B. The items/reports identified shall be addressed and delivered to the GPO in the quantities stated. An electronic copy of the Final Report shall also be submitted to the GPO.
In addition, one (1) copy of each Quarterly Study Report and one (1) copy of the Final Report shall be delivered to the Contracting Officer by the specified delivery date.

C. The following FAR Clauses applies to this contract and are incorporated by reference with the same force and effect as is set forth in the full text.

FAR CLAUSE	TITLE AND DATE
52.242.15	Stop Work Order (August 1989), Alternate I (April 1984)

52.246-8	Inspection of Research and Development – Cost Reimbursement (April 1984)

ATTACHMENT 3 to STREAMLINED RFP No. NIMH-00-DS-0004

EVALUATION FACTORS FOR CONTRACT AWARD

1. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria.

- ACCESS TO STUDY SUBJECTS

  Offerors must demonstrate that they have access to the children who participated at their site in the MTA study and provide evidence that they can prospectively assess an adequate number of children and families necessary for reaching the study aims.

- EVALUATION OF REPRESENTATION OF MINORITY GROUPS, GENDER, AND CHILDREN

  This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

  Where inclusion of women and minority populations and/or children is not feasible, a detailed rationale and justification for exclusion of one or more groups from the study population must be submitted with the technical proposal. The NIH will review the exclusion rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are being considered for award, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision. If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered for further award.

  Investigators should read "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", in the NIH Guide for Grants and Contracts, March 18, 1994, URL: http://grants.nih.gov/grants/guide/notice-files/not94-100.html; and "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects", in the NIH Guide for Grants and Contracts, March 6, 1998, URL: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

The offeror shall provide an index within its proposal which directs the reviewer(s) to the specific area(s) of the proposal that address a particular mandatory qualification. The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

2. GENERAL

The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the RFP. The merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. Proposals which merely offer to conduct a project in accordance with the requirements of the Government's scope of work will be considered non-responsive to this request and will not be considered further. The offerors must submit an explanation of the technical approach and a detailed description of the tasks to be performed to achieve the project objectives.

Because this is a multi-site study, offerors are to develop and submit only one technical proposal that describes the work to be conducted at all sites with separate sections on personnel and resources that are specific to each site. In addition, each site shall submit a separate business proposal specific to its site.

At a minimum, the proposal shall include the following:

a. A detailed explanation of the value of following up the MTA sample vis-à-vis the ability to address as many as possible of the following questions:

I. What is the impact over time of the 14-month exposure to treatment modalities, which were different in type and intensity, on:

- Persistence of ADHD symptoms
- Incidence of psychopathology (i.e., non-ADHD psychiatric disorders, such as depression, mania, psychosis)
- Incidence of early substance use, substance abuse, and substance dependence (targeted as separate outcomes)
- Incidence of delinquent behaviors
- Educational achievement
- Incidence of other adverse outcomes (harm from accidents, suicidal behaviors, aggressive acts)
- Utilization of mental health and medical services
- Utilization of court-mandated services
- Utilization of special education services

II. How do the services actually received compare, in terms of type and quality, to the "ideal standard" set by the treatment received during the clinical trial?

III. What are the possible moderators and mediators of obtaining (or not obtaining) appropriate and adequate mental health and educational services? For instance, the following could be considered:

- structural (e.g., access barriers, coordination, comprehensiveness)
- parent/child characteristics (e.g., income, insurance status, education; attitudes, knowledge, cultural factors; degree of improvement at the end of the controlled clinical trial)?
- process of care factors (e.g., continuity; technical, interpersonal aspects; participatory decision making)
- perceived outcomes

IV. What are the cost implications (e.g., cost/benefit ratios) of intensive treatments for children with ADHD? How do these treatment costs relate to costs later expended in special education, juvenile justice, mental health, or substance abuse settings?

V. What is the impact of 14-month sustained treatment of prepubertal ADHD children with high, moderate, and low doses of amphetamine-like stimulants on:

1. Risk for anxiety, mood disorders, tics, eating disorders

2. Risk for substance abuse and dependence

3. Growth (growth speed, puberty)

b. A detailed explanation of the methods (including information to be collected, informants, raters, rating instruments, frequency of assessments, and other relevant information) that are proposed for the follow-up of the MTA sample.

c. Plans to maintain the study sample and reduce attrition.

d. A discussion of the identified or expected shortcomings and limitations of the sample, their possible impact on the ability to address any of the research questions, and proposed strategies to obviate, as much as possible, these limitations.

3. RELATIVE IMPORTANCE OF TECHNICAL AND COST FACTORS

Award will be made based on technical and cost factors. Paramount consideration shall be given to the evaluation of the technical proposals, but not to the exclusion of cost considerations. While high competency is sought, capabilities that exceed those needed for successful performance of the contract work/statement are not requested. In the event that the technical evaluation reveals that multiple Offerors are approximately equal in technical ability, then the estimated cost of performance

will become paramount. Proposals are intended to be evaluated and award made after discussions with Offerors, but an award may be made without discussions with Offerors.

4. TECHNICAL EVALUATION CRITERIA

Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted in order of their relative importance. Proposals will be judged solely on the written material provided by the Offeror.

WEIGHT	CRITERIA
60	**TECHNICAL APPROACH**

The proposal should demonstrate:

Soundness and practicality of the technical approach for answering as many as possible of the main research questions, with adequate justification and substantiation for the recommended methods; also, demonstration of Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. The evaluation will assess:

a. Scientific value of the proposed study protocol. The Offerors should develop and fully elaborate the key elements of the study design . A detailed protocol clearly outlining the proposed experimental methodology should be an integral part of each proposal, including, but not limited to, the following aspects:

o Elaboration of the research questions and discussion of any previous data and literature;
o Power analysis;
o Description of the proposed approach to accomplish the study aims;
o Proposed assessment measures and their frequency of administration;
o Plans for sample maintenance
o Plans for ensuring consistent and replicable assessment of the clinical variables of interest within and across sites during the duration of the study
o Plans for ensuring quality control of the data collection;
o Data analysis

25 PERSONNEL AND MANAGEMENT PLAN

The Offeror shall demonstrate that they have staff with appropriate training, expertise, experience, and availability to plan and implement this project as described in the Work Statement. The proposed staff should have substantial research experience in the assessment of children with ADHD and their families. The Principal Investigator should be experienced in ADHD treatment research and available for providing adequate input to the research activities.

15 FACILITIES, EQUIPMENT AND RESOURCES

Adequacy and availability of the facilities, equipment and resources necessary for conducting the proposed work.

5. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provisions(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

ATTACHMENT 4 TO STREAMLINED RFP No. NIMH-00-DS-0004

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. JUST IN TIME

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the discussion process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from the apparent successful offeror(s). The special procedures for submission of this documentation are set forth below:

Travel Policy, Annual Report, Total Compensation Plan and Subcontracting Plan: All apparent successful offerors will be required to submit these documents as part of their FPR.

Cost Pricing Information: The offeror's business proposal shall include the basic cost/pricing information specified in Paragraph N, "Business Proposal Instructions" subparagraph 2, "Cost and Pricing Data" of this RFP. In addition, the government may require apparent successful offerors to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested during negotiations, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. (The information may also include submission and certification of cost or pricing data.)

B. SIC CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The standard industrial classification (SIC) code for this acquisition is 8093.

2. The small business size standard is $5 Million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation (except for foreign acquisitions), the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

C. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that the awards from this solicitation will be multiple year Cost Reimbursement, Completion type contracts with a Period of Performance of 5 years with one - two year option and that incremental funding will be used. It is anticipated that a total of 7 non-competitive awards will be made.

D . COMMITMENT OF PUBLIC FUNDS

The CO is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

E . COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the CO cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

F . RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

G. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in Attachment 3 of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

H. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

I. SERVICE OF PROTEST (AUGUST 1996) – FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the CO (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

If hand-delivered or delivery service	If using U.S. Postal Service
National Institute of Mental Health	National Institute of Mental Health

Contracts Management Branch
Attn: Contracting Officer
6001 Executive Boulevard
Room 6107, MSC 9603
Rockville, Maryland 20852

Contracts Management Branch
Attn: Contracting Officer
6001 Executive Boulevard,
Room 6107, MSC 9603
Bethesda, Maryland 20892-9603

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

J. SAFETY AND HEALTH (DEVIATION) PHS 352.223-70 (Aug 1997)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

K. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE OF HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72.

(a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

2. INSTRUCTIONS TO OFFERORS

L . GENERAL INSTRUCTIONS

The following instructions will establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. Also, please note that the technical proposal must be organized and presented in accordance with the "Technical Proposal Instructions " (Paragraph M. below).

(1) **Type Contract and General Clauses**

It is contemplated that a cost-reimbursement/completion type contract will be awarded. (See General Information). Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the address in the attached solicitation cover letter, and mark each package as follows: RFP No. NIMH-00-DS-0004 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

(a) COVER SHEET

Include RFP number, title, name of organization, name of Principal Investigator, names of other offeror key personnel, name of any subcontractor(s) and their proposed Principal Investigator(s), names of any collaborators or consultants, and indicate whether the proposal is an original or a copy.

(b) TECHNICAL PROPOSAL

Format and organization of the technical proposal must follow the Table of Contents, and must include the information requested in the Technical Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(c) BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 5).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resource information, such as labor-hours and categories, materials, subcontracts, travel, etc, and associated cost so that the offeror's understanding of the project may be evaluated. (See Attachment 5). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided , that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Confidentiality of Proposals (HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984))**

The proposal submitted in response to this RFP may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act, and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal; the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."

NOTE: Offerors are cautioned that proposals submitted with the restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 3, “Evaluation Factors for Contract Award”.

(8) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the CO determines that the initial prices are fair and reasonable and that discussions are not necessary.

(9) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon(as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(10) **Human Subjects**

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR, (telephone: 301-496-7041), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(11) **Privacy Act**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and, as applicable, P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

The System of Records applicable to this requirement may be accessed at URL: http://www.nimh.nih.gov/grants/privacyact1997.pdf

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all from this RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(13) **Small Business Subcontracting Plan**

******* This document is INCLUDED in the "Just In Time" procedures. *******

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan and Attachment 5 to the RFP.

(14) Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from Federal Register dated March 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Refer to Attachment 5 of the RFP for information on where to obtain a copy of this Guide.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a gender specific study or a single or limited number of minority population groups. Therefore, the NIMH believes that the inclusion of women and minority populations is appropriate for this project. (Refer to Attachment 3 of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report Format for Each Study (See Attachment 5 of this RFP) shall be used in proposal preparation.

(15) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998, see Attachment 5 of this RFP for information on where to obtain a copy of this Guide.

(16) **Salary Rate Limitation in Fiscal Year 2000**

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The salary rate limitation set by P.L. 106-113 applies only to Fiscal Year 2000 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in

future appropriations acts. The Executive Schedule, Level II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level II."

***This rate may change periodically. For your information, the rate can be found at URL: http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm**

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and(2) in the case

of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

(1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with the regulations.

(18) **Institutional Management of Conflicting Interests**

(1) The designated official(s) must: (i) review all financial disclosures; and(ii) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i. public disclosure of significant financial interests;
ii. monitoring of research by independent reviewers;
iii. modification of the research plan;
iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v . divestiture of significant financial interests; or
vi. severance of relationships that create actual or potential conflicts of interests.

(2) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (1) of this section, as the Institution deems appropriate.

(19) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (i) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (ii) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(20) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates the following solicitation provisions by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
b. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
c. Order of Precedence - Uniform Contract Format, FAR Clause 52.215-8 (October 1997)
d. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000) FAR Clause 52.222-24, (February 1999)
e. Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data, FAR 52.215-20 (October 1997)

M. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted for each proposed objective indicating how each aspect of the objective is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to fully explain your proposed technical approach and methodology. The technical proposal should reflect a clear understanding of the nature of the work being undertaken and must include information on how the project is to be organized, staffed, and managed. The Technical Proposal should be organized and presented as stated below.

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a. **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the Statement of Work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the CO. Unless the RFP indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar

equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. If the Principal Investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. Resumes must not exceed two pages.

c. **Facilities and Resources**

List/describe all facilities and resources available for this project, including any equipment.

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into and between the twentieth and twenty-first centuries and Year 1999 and Year 2000 and leap year calculations.

d. **Summary of Related Activities**

The offeror shall complete and include with the technical proposal the "Summary of Current and Proposed Activities" form, see Attachment 5, of this RFP. Include this form with the Other Considerations portion of your technical proposal.

2. **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Evaluation Factors for Contract Award (Attachment 3).

3. **Additional Technical Proposal Information**

a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by the initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

(a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the Statement of Work will be accomplished within this working relationship.

(b) Unique arrangements which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

(c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

(d) Other factors you feel are important and support your proposed research.

(e) Recommendations for changing reporting requirements or other deliverables if such changes would be more compatible with the offeror's proposed schedules.

N. BUSINESS PROPOSAL INSTRUCTIONS

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Cost and Pricing Data**

(a) General Instructions

(1) You must provide the following information on the first page of your pricing proposal:

(i) Solicitation, contract, and/or modification number;
(ii) Name and address of offeror, to include DUNS number;
(iii) Name and telephone number of point of contact;
(iv) Name of contract administration office (if available);
(v) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(vi) Proposed cost; profit or fee; and total;
(vii) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(viii) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been

determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(ix) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the CO and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(x) Date of submission; and
(xi) Name, title and signature of authorized representative.

(b) In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

(c) As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

(d) You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed research objective, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" (see paragraph 3 below). You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

(e) When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

(f) Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

(g) If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

(h) As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

3. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

(a) Direct Labor

Provide a time-phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for estimates.

(b) Fringe Benefits

Show fringe benefits as a separate line item. Include the rates(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or organizational guidelines.

(c) Materials and services

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2, below. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.)

exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR31.205-26(e)).

(2) All Other. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The CO may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

(d) Indirect Costs

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

(e) Special Equipment

If direct charge, list any equipment proposed including description, price, quantify, total price, purchase of lease, and the basis for pricing.

(f) Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

(g) Other Costs

List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

(h) Royalties

If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

(i) Facilities Capital Cost of Money (Commercial Organizations, only)

When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

4. **Formats for Submission of Line Item Summaries**

A separate cost/price estimate shall be provided for each research objective that you may propose. Individual cost/price estimates shall be furnished in accordance with the detailed breakdown in the format similar to that shown on the "Business Proposal Cost Information" form, see Attachment 5 of this RFP. For each separate cost/price estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. Further, in an effort to assist the cost proposal review process, Offerors who have prepared their business proposal using the following software spreadsheet programs

are requested to provide a copy of the cost proposal spreadsheet(s) on a computer disk (high density) along with the submission of your paper copies of the business proposal. IBM PC compatible software programs are: Excel; Lotus 1-2-3; and Quattro Pro.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at URL: http://amb.nci.nih.gov/cpi.htm

5. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the CO or an authorized representative. As later information comes into your possession, it should be submitted promptly to the CO in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

6. By submitting your proposal, you grant the CO or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price. [Note to Offerors of RFPs using "JUST IN TIME" procedures: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

7. Total Compensation Plan - Instructions

********* ***This document is INCLUDED in the "Just In Time" procedures.*** **********

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN DISCUSSIONS WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be

evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

8. **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

9. **Qualifications of the Offeror**

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and,

while not a specific weighted evaluation factor, they are inherent in one or more technical evaluation criterion. Also, they may be used to conduct a relative assessment of offerors during the source selection process if the evaluation factors for contract award, in the specific RFP so indicate.

10. **Property, Equipment, Facilities**

(a) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the CO. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes, in addition to the description and estimated cost of each item:

(1) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(2) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(b) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(c) If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the CO having cognizance of the property for use of that property without charges; (3) Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

(d) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

11. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

12. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

13. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

14. **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the FAR clause 52.232.22, entitled "Limitation of Funds." Under that clause,

which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

15. **Facilities Capital Cost of Money, FAR 52.215-16 (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by including one of the following statements:

-The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10), or

-The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

16. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

(a) Willingness to perform as a subcontractor for specific duties (list duties).
(b) What priority the work will be given and how it will relate to other work.
(c) The amount of time and facilities available to this project.

(d) Information on their cognizant field audit offices.
(e) How rights to publications and patents are to be handled.
(f) A complete cost proposal in the same format as the offeror's cost proposal.

17. **Representations and Certifications**

One copy of the Representations and Certifications shall be completed and signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. (See Attachment 5 of this RFP.)

PROPOSAL INTENT RESPONSE SHEET - PROPOSAL INTENT
RFP NIMH-00-DS-0004

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE June 16, 2000. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.
CHECK ONLY ONE BOX.

[] DO INTEND TO SUBMIT A PROPOSAL

[] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)
_____
_____
_____
_____

TO: National Institute of Mental Health
Contracts Management Branch
Attn: Robert D. Barnie
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603
FAX (301) 443-0501
Rb245s@nih.gov

ATTACHMENT 5 TO STREAMLINED RFP No. NIMH-00-DS-0004

APPLICABLE RFP REFERENCES

A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Contract with an Educational Institution, Negotiated Cost-Reimbursement Contract with a Non-Profit or, Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file General Clauses " at URL: http://amb.nci.nih.gov/Clauses/Clauses.html.

B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) FORMS, FORMATS AND ATTACHMENTS at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.
2. Business Proposal Cost Information
3. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
4. Representations and Certifications - Negotiated Contract, only one completed and signed copy

OTHER - TO BE SUBMITTED LATER:

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, if required by the CO
2. DHHS Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan, to be submitted as directed by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

1. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions
3. Procurement of Certain Equipment, NIH(RC)-7
4. NIH Women and Minority Policy
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF310
6. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects
7. Annual Technical Progress Report Format for Each Study

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file entitled, FORMS, FORMATS AND ATTACHMENTS at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm. Supplemental information pertaining to Sections G & H of the Sample Contract Format include the following:

1. Section G, "Invoice Submission" is amended to read as follows:

Invoice Submissions/Contract Financing Request

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated billing office:

If hand-delivered or delivery Service	If using U.S. Postal Service
Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Rockville, Maryland 20852	Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 6107, MSC 9603 Bethesda, Maryland 20892-9603

Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

b. At a minimum, the Contractor agrees to include the following information on each invoice:

1. Contractor's name and invoice date,
2. NIMH's Contract number, or other authorization for delivery of property and/or services
3. Description, cost or price, and quantity of property and/or services actually delivered or rendered,
4. Shipping and payment terms,
5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below,
6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:

(a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) Fringe Benefits - Cite rate and amount
(c) Overhead - Cite rate and amount
(d) Materials & Supplies - Include detailed breakdown.
(e) Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.
(f) Consultant Fees - Identify individuals and amounts.
(g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
(h) Equipment - Cite authorization and amount.
(i) G&A - Cite rate and amount.
(j) Total Cost
(k) Fee (if applicable)
(l) Total Cost & Fee

Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2. The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

2. Section H "Human Subject" is amended to read as follows:

H. Human Subjects

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by, both your local Internal Review Board (IRB) and the NIMH Data Safety Monitoring Board, written notice of such approval has been provided by the NIMH Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.